

REMARKS

In the present communication, claim 2 has been amended; claims 14-17 have been canceled; and no claims have been added. The amendments add no new matter and are fully supported by the specification and claims as filed. Upon entry of the present amendment, claims 2-4, 7, 9-10, 13 and 19 will be pending in this application.

Rejections under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 14-17 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office Action alleges that claims 14-17 contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the invention. Without acquiescing to the reasoning presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have canceled claims 14-17 without prejudice or disclaimer rendering the rejection moot.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C §102

Applicants respectfully traverse the rejection of claims 2, 4, 7, 9-10, 13 and 19 under 35 U.S.C. §102(b), as allegedly anticipated by Lin et al. (*Nature*, 410: 84-88 (March 1, 2001)). To anticipate, a single reference must inherently or expressly teach each and every element of the claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

Specifically, the Office Action alleges, that Lin et al. teach each of the active steps of the claimed method including contacting a neuronal cell with a test compound and assaying the ability of the test compound to modulate the expression of GTRAP3-18 protein expression and activity as determined by glutamate transport (EAAC1) activity.

Without acquiescing to the rationale presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 2 to recite "a method for identifying a compound which modulates cellular glycosylation, comprising: a) contacting a cell which expresses GTRAP3-18 with a test compound; and b) identifying the test compound as a modulator of cellular glycosylation by assaying the ability of the test compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide, thereby identifying a compound which modulates cellular glycosylation."

Applicants respectfully submit that Lin et al. fail to teach a method for identifying a compound which modulates cellular glycosylation as recited. Lin et al. fail to teach identifying a test compound as a modulator of cellular glycosylation as recited in b) of amended claim 2. Further, Applicants respectfully submit that Lin et al. is silent with respect to the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation. Applicants point out that where "the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Applicants submit that the preamble of claim 2 recites "a method for identifying a compound which modulates cellular glycosylation" and when read in the context of the entire claim which includes identification of such a compound, the claim clearly includes limitations not disclosed in Lin et al.

Additionally, in "determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'...." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). Furthermore, a reference contains an "enabling disclosure" if the public was in

possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). MPEP §2121.01.

Applicants respectfully submit that Lin et al. is not available as prior art under 35 U.S.C. §102 because the reference does not include an enabling disclosure. Lin et al. does not teach a method for identifying a compound which modulates cellular glycosylation as recited. Since Lin et al. fail to teach the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation, the public was not in possession of a method of identifying a test compound as a modulator of cellular glycosylation by assaying the ability of the test compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide. Additionally, one of ordinary skill in the art could not have combined the description of Lin et al. with their own knowledge to make the claimed invention because the role of GTRAP3-18 in cellular glycosylation was previously unclear.

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Applicants respectfully traverse the rejection of claims 2, 4, 7, 9, 13 and 19 under 35 U.S.C. §102(e), as allegedly anticipated by U.S. Patent No. 6,808,893 (Rothstein et al.).

Specifically, the Office Action alleges, that Rothstein et al. teach each of the active steps of the claimed method including contacting a neuronal cell with a test compound and assaying the ability of the test compound to modulate the expression of GTRAP3-18 protein expression.

Without acquiescing to the rationale presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 2 to recite "a method for identifying a compound which modulates cellular glycosylation, comprising: a) contacting a cell which expresses GTRAP3-18 with a test compound; and b) identifying the test compound as a modulator of cellular glycosylation by assaying the ability of the test compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide, thereby identifying a compound which modulates cellular glycosylation."

Applicants respectfully submit that Rothstein et al. fail to teach a method for identifying a compound which modulates cellular glycosylation as recited. Rothstein et al. fail to teach identifying a test compound as a modulator of cellular glycosylation as recited in b) of amended claim 2. Further, Applicants respectfully submit that Rothstein et al. is silent with respect to the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation. Applicants point out that where "the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Applicants submit that the preamble of claim 2 recites "a method for identifying a compound which modulates cellular glycosylation" and when read in the context of the entire claim which includes identification of such a compound, the claim clearly includes limitations not disclosed in Rothstein et al.

Additionally, as discussed previously, to render a reference anticipated, the reference must include an enabling disclosure. MPEP §2121.01. Applicants respectfully submit that Rothstein et al. is not available as prior art under 35 U.S.C. §102 because the reference does not include an enabling disclosure. Rothstein et al. does not teach a method for identifying a compound which modulates cellular glycosylation as recited. Since Rothstein et al. fail to teach the correlation between GTRAP3-18 activity regulation or expression with modulation of cellular glycosylation, the public was not in possession of a method of identifying a test compound as a modulator of cellular glycosylation by assaying the ability of the test compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide. Additionally, one of ordinary skill in the art could not have combined the description of Rothstein et al. with their own knowledge to make the claimed invention because the role of GTRAP3-18 in cellular glycosylation was previously unclear.

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Rejections under 35 U.S.C §103(a)

Applicants respectfully traverse the rejection of claims 3 and 13 under 35 U.S.C. §103(a), as allegedly obvious over Lin et al. as applied to claims 2, 4, 7, 9-10 and 13, and further in view of Hirabayashi et al. (*Journal of Chromatography B*, 771: 67-87 (May 5, 2002)).

The recent U.S. Supreme Court decision in *KSR International v. Teleflex Inc.* (82 USPQ 2d 1385), modified the standard for establishing a *prima facie* case of obviousness. Under the *KSR* rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

As discussed above, without acquiescing to the rationale presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 2, from which claims 3 and 13 depend, to recite “a method for identifying a compound which modulates cellular glycosylation, comprising: a) contacting a cell which expresses GTRAP3-18 with a test compound; and b) identifying the test compound as a modulator of cellular glycosylation by assaying the ability of the test compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide, thereby identifying a compound which modulates cellular glycosylation.”

The Examiner alleges that Lin et al. teach antisense oligomer and retinoic acid modulation of GTRAP3-18 protein expression and activity as determined by glutamate transport via coexpressed EAAC1. However, Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness because the cited references fail to provide some suggestion or motivation to modify a reference or combine the teachings of the reference to arrive at the claimed invention. As discussed above, Lin et al. fail to provide a method of identifying a modulator of cellular glycosylation as claimed. Further, Lin et al. fail to teach or suggest a correlation between GTRAP3-

18 activity regulation or expression and modulation of cellular glycosylation as claimed. The teachings of Hirabayashi et al. fail to remedy the deficiency.

Applicants submit that even if one were to combine the teachings of Lin et al. and Hirabayashi et al., the resulting combination would not be *prima facie* obvious over the claimed invention since the combined teachings fail to disclose each and every claim limitation. As discussed above, Applicants respectfully submit that both Lin et al. and Hirabayashi et al. fail to teach a method for identifying a compound which modulates cellular glycosylation as recited because they do not teach identifying a test compound as a modulator of cellular glycosylation as recited in b) of amended claim 2. Further, Applicants respectfully submit that both Lin et al. and Hirabayashi et al. are silent with respect to the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation.

Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

In re Application of
Rothstein and Ruggiero
Application No.: 10/542,435
Filed: May 2, 2006
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Attorney Docket No.: JHU2090-1

Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge the total amount of \$470.00 as payment for the Request for Continued Examination fee (\$405.00) and One-Month Extension of Time fee (\$65.00), for small entity, to Deposit Account No. 07-1896. The Commissioner is further authorized to credit any additional fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,



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